# PATENT COOPERATION TREATY

РСТ	From the INTERNATIONAL BUREAU To:
NOTIFICATION OF THE RECORDING OF A CHANGE  (PCT Rule 92bis.1 and Administrative Instructions, Section 422)  Date of mailing (day/month/year) 30 August 2001 (30.08.01)	MILLER, Mary, L. Needle & Rosenberg, P.C. Suite 1200 127 Peachtree Street, N.E. Atlanta, GA 30303-1811 ETATS-UNIS D'AMERIQUE
Applicant's or agent's file reference 14114.0353P1 International application No.	IMPORTANT NOTIFICATION  International filing date (day/month/year)
PCT/US00/07828	24 March 2000 (24.03.00)
Name and Address  THE GOVERNMENT OF THE UNITED STATES OF AMERICA as represented by THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention Technology Transfer Office 1600 Clifton Road, N.E. MS E-67 Atlanta, GA 30333 United States of America	State of Nationality State of Residence US US Telephone No.  Facsimile No.  Teleprinter No.
4. A copy of this notification has been sent to:  X the receiving Office the International Searching Authority X the International Preliminary Examining Authority	the designated Offices concerned  X the elected Offices concerned  other:
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland acsimile No.: (41-22) 740.14.35	Authorized officer  Beatriz LARGO  Telephone No.: (41.32) 328 82.39

Form PCT/IB/306 (March 1994)

004252924

## PATENT COOPERATION TREATY

	From the INTERNATIONAL BUREAU
PCT	То:
NOTIFICATION OF ELECTION (PCT Rule 61.2)	Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202
Date of mailing (day/month/year) 07 November 2000 (07.11.00)	ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No. PCT/US00/07828	Applicant's or agent's file reference 68018
International filing date (day/month/year) 24 March 2000 (24.03.00)	Priority date (day/month/year) 31 March 1999 (31.03.99)
Applicant	
OBERSTE, Steven et al	
in a notice effecting later election filed with the Inte	2000 (17.10.00)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Charlotte ENGER

Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

Facsimile No.: (41-22) 740.14.35

US0007828





(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER see Notification o	f Transmittal of International Search Report
68018	ACTION (Form PCT/ISA/2)	20) as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/US 00/07828	24/03/2000	31/03/1999
Applicant		
THE COVERNMENT OF THE UNIT	TED CTATES OF MILES	
THE GOVERNMENT OF THE UNI	TED STATES OF AMERICA as	
according to Article 16. A copy is being tra		ority and is transmitted to the applicant
This International Search Report consists  It is also accompanied by	of a total of sheets. a copy of each prior art document cited in this	report.
Basis of the report		
With regard to the language, the in language in which it was filed, unle	nternational search was carried out on the basi ess otherwise indicated under this item.	s of the international application in the
Authority (Rule 23.1(b)).	as carried out on the basis of a translation of th	
b. With regard to any nucleotide and was carried out on the basis of the	d/or amino acid sequence disclosed in the int sequence listing:	ernational application, the international search
	nal application in written form.	
	national application in computer readable form	•
1 555	this Authority in written form.	
l <del></del>	this Authority in computer readble form.	
international application as	sequently furnished written sequence listing do filed has been furnished.	es not go beyond the disclosure in the
X the statement that the infor furnished	mation recorded in computer readable form is	identical to the written sequence listing has been
2. Certain claims were foun	d unsearchable (See Box I).	
3. Unity of invention is lack	•	
4. With regard to the title,	,	
X the text is approved as sub	mitted by the applicant.	
	ed by this Authority to read as follows:	
5. With regard to the abstract,		
the text is approved as sub the text has been establish within one month from the c	mitted by the applicant. ed, according to Rule 38.2(b), by this Authority date of mailing of this international search repo	as it appears in Box III. The applicant may, tt, submit comments to this Authority.
6. The figure of the <b>drawings</b> to be publis		
as suggested by the applica		X None of the figures.
because the applicant failed	d to suggest a figure.	
because this figure better c	haracterizes the invention.	



A. CLASSIFICATION OF SUBJECT IPC 7 C12Q1/70	MAT.ER

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

 $\begin{tabular}{ll} \begin{tabular}{ll} Minimum documentation searched (classification system followed by classification symbols) \\ IPC 7 C12Q \\ \end{tabular}$ 

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, MEDLINE

Citation of document, with indication, where appropriate, of the relevant passages   Relevant	
(US)) 9 April 1998 (1998-04-09)  4 figures 1,2   7-17, 20-39 43,44 7,8,1 19, 40-42 45,46	to claim No.
A figures 1,2 7,8,1 19, 40-42 45,46	,
	8,

Further documents are listed in the continuation of box C.	χ Patent family members are listed in annex.
Special categories of cited documents:      A' document defining the general state of the art which is not considered to be of particular relevance      E' earlier document but published on or after the international filling date      L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)      O' document referring to an oral disclosure, use, exhibition or other means      P' document published prior to the international filling date but later than the priority date claimed	<ul> <li>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>*&amp;* document member of the same patent family</li> </ul>
Date of the actual completion of the international search  12 July 2001	Date of mailing of the international search report  24/07/2001
Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL – 2280 HV Rijswijk  Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,  Fax: (+31–70) 340–3016	Authorized officer  Van Klompenburg, W

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C (Continue	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	1/03 00/0/828
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	OBERSTE ET AL.: "Molecular evolution of the human enteroviruses: correlation of serotype with VP1 sequence and application to picornavirus classification" JOURNAL OF VIROLOGY, vol. 73, no. 3, 11 February 1999 (1999-02-11), pages	1-6, 9-17, 20-39, 43,44
A	1941-1948, XP002171810 figures 1,3; table 2	7,8,18, 19, 40-42, 45,46
Ρ,Χ	OBERSTE ET AL.: "Typing of human enteroviruses by partial sequencing of VP1"  JOURNAL OF CLINICAL MICROBIOLOGY, vol. 37, no. 5, May 1999 (1999-05), pages 1288-1293, XP002171811 abstract; figures 1,2; table 1	1-5, 9-16, 20-39, 43,44
P,X	WO 99 53097 A (US HEALTH ;KILPATRICK DAVID R (US)) 21 October 1999 (1999–10–21)  claims 1–6; examples 1–3; tables 1–5  ————	1-5, 9-16, 20-39, 43,44

Information on patent family members

International Application No
/US 00/07828

Patent document cited in search repor	t	Publication date	Patent family member(s)	Publication date
WO 9814611	A	09-04-1998	AU 4663997 A EP 0932702 A JP 2001501822 T US 6168917 B	24-04-1998 04-08-1999 13-02-2001 02-01-2001
WO 9953097	Α	21-10-1999	AU 3383799 A	01-11-1999

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION T

(19) World Intellectual Property Organization International Bureau



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(43) International Publication Date 5 October 2000 (05.10.2000)

(10) International Publication Number WO 00/58524 A3

(51) International Patent Classification7:

PCT/US00/07828 (21) International Application Number:

(22) International Filing Date: 24 March 2000 (24.03.2000)

(25) Filing Language:

English

C12Q 1/70

(26) Publication Language:

English

(30) Priority Data: 60/127,464

31 March 1999 (31.03.1999) US

- (71) Applicant (for all designated States except US): THE GOVERNMENT OF THE UNITED STATES OF AMERICA as represented by THE SECRETARY, DE-PARTMENT OF HEALTH AND HUMAN SERVICES [US/US]; Centers for Disease Control and Prevention. Technology Transfer Office, 1600 Clifton Road, N.E. MS E-67, Atlanta, GA 30333 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): OBERSTE, Steven [US/US]; 5110 Sunset Maple Trail, Lulburn, GA 30047 (US). MAHER, Kaija [US/US]; 3014 Silvapine Trail, Atlanta, GA 30345 (US). KILPATRICK, David, R. [US/US]: 1095 Fulton Court, Norcross, GA 30093-4041 (US). PALLANSCH, Mark, A. [US/US]; 4749 Mockernut Court, Lilburn, GA 30047 (US).

- (74) Agent: MILLER, Mary, L.; Needle & Rosenberg, P.C., Suite 1200, 127 Peachtree Street, N.E., Atlanta, GA 30303-1811 (US).
- (81) Designated States (national): AE. AG. AL. AM. AT. AU. AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE. DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID. IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT. TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

#### Published:

with international search report

(88) Date of publication of the international search report: 2 May 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: TYPING OF HUMAN ENTEROVIRUSES

(57) Abstract: The present invention discloses a method for detecting the presence of an enterovirus in a clinical sample. The invention additionally discloses a method for typing an enterovirus in a clinical sample. Both methods employ a set of primer oligonucleotides for reverse transcription and amplification that hybridize to conserved regions of the enterovirus genome, and that provide amplicons that include significant portions of the VP1 region that are characteristic of the various serotypes. In the typing method, the invention further provides a database consisting of nucleotide sequences from prototypical enteroviral serotypes, which is used to type the clinical sample by comparing the sequence of its amplicon with each prototypical sequence in the database. The invention additionally provides mixtures of primer oligonucleotides, and a kit for use in conducting the typing method that includes a mixture of the primer oligonucleotides.

### FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
ВВ	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
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CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

~ational Application No Pui/US 00/07828

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C12Q1/70

RECEIVED

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q JUN 0 3 2002 TECH CENTER 1600/2900

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, MEDLINE

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
(	WO 98 14611 A (US HEALTH ;KILPATRICK DAVID (US)) 9 April 1998 (1998-04-09)	1-6, 9-17, 20-39, 43,44
A	figures 1,2	7,8,18, 19, 40-42, 45,46
	-/	

Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents:  A* document defining the general state of the art which is not considered to be of particular relevance  E* earlier document but published on or after the international filing date  L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  O* document referring to an oral disclosure, use, exhibition or other means  P* document published prior to the international filing date but later than the priority date claimed	<ul> <li>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention.</li> <li>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.</li> <li>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>"&amp;" document member of the same patent family</li> </ul>
Date of the actual completion of the international search	Date of mailing of the international search report
12 July 2001	24/07/2001
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	van Klompenburg, W

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ation) DOCUMENTS CONSIDERED TO BE RELEVANT	Relevant to claim No.
Citation of document, with indication, where appropriate, of the relevant passages	Ticlovani io Gain 140.
OBERSTE ET AL.: "Molecular evolution of the human enteroviruses: correlation of serotype with VP1 sequence and application to picornavirus classification" JOURNAL OF VIROLOGY, vol. 73, no. 3, 11 February 1999 (1999-02-11), pages	1-6, 9-17, 20-39, 43,44
figures 1,3; table 2	7,8,18, 19, 40-42, 45,46
OBERSTE ET AL.: "Typing of human enteroviruses by partial sequencing of VP1"  JOURNAL OF CLINICAL MICROBIOLOGY, vol. 37, no. 5, May 1999 (1999-05), pages 1288-1293, XP002171811 abstract; figures 1,2; table 1	1-5, 9-16, 20-39, 43,44
WO 99 53097 A (US HEALTH ;KILPATRICK DAVID R (US)) 21 October 1999 (1999-10-21)  claims 1-6; examples 1-3; tables 1-5	1-5, 9-16, 20-39, 43,44
	OBERSTE ET AL.: "Molecular evolution of the human enteroviruses: correlation of serotype with VP1 sequence and application to picornavirus classification" JOURNAL OF VIROLOGY, vol. 73, no. 3, 11 February 1999 (1999-02-11), pages 1941-1948, XP002171810 figures 1,3; table 2  OBERSTE ET AL.: "Typing of human enteroviruses by partial sequencing of VP1" JOURNAL OF CLINICAL MICROBIOLOGY, vol. 37, no. 5, May 1999 (1999-05), pages 1288-1293, XP002171811 abstract; figures 1,2; table 1  WO 99 53097 A (US HEALTH; KILPATRICK DAVID R (US)) 21 October 1999 (1999-10-21)

1

Information on patent family members

Intrational Application No PUT/US 00/07828

Patent document cited in search repor	t	Publičation date	Patent family member(s)	Publication date
WO 9814611	A	09-04-1998	AU 4663997 A EP 0932702 A JP 2001501822 T US 6168917 B	24-04-1998 04-08-1999 13-02-2001 02-01-2001
WO 9953097	A	21-10-1999	AU 3383799 A	01-11-1999

### PATENT COOPERATION TREATY

NEEDLE & ROSENBERG

From the INTERNATIONAL BUREAU **PCT** To:

MILLER, Mary, L.

NOTIFICATION OF THE RECORDING OF A CHANGE

Needle & Rosenberg, P.C. **Suite 1200** (PCT Rule 92bis.1 and 127 Peachtree Street, N.E. Administrative Instructions, Section 422) Atlanta, GA 30303-1811 **ETATS-UNIS D'AMERIQUE** Date of mailing (day/month/year) 17 July 2001 (17.07.01)

Applicant's or agent's file reference IMPORTANT NOTIFICATION 14114.0353P1 International application No. International filing date (day/month/year) 24 March 2000 (24.03.00) PCT/US00/07828

1. The following indications appeared on record concerning:	the common representative
Name and Address  SAMPLES, Kenneth, H. Fitch, Even, Tabin & Flannery Suite 1600 120 South LaSalle Street Chicago, IL 60603 United States of America	t the common representative  State of Nationality State of Residence  Telephone No. 312 577 7000  Facsimile No. 312 577 7007  Teleprinter No.
2. The International Bureau hereby notifies the applicant that the following  X the person  X the name  X the address	change has been recorded concerning: the nationality the residence
MILLER, Mary, L. Needle & Rosenberg, P.C. Suite 1200 127 Peachtree Street, N.E. Atlanta, GA 30303-1811 United States of America  WMBAB/7MH  DOCKETED  Date/2  Reviewed Name/Date	Telephone No. 501 (404) 688-0770 Facsimile No. 404) 688-9880 Teleprinter No.
3. Further observations, if necessary: Please also note the new agent's file reference.	
4. A copy of this notification has been sent to:  X the receiving Office the International Searching Authority  X the International Preliminary Examining Authority  [ ]	the designated Offices concerned  X the elected Offices concerned  X other: SAMPLES, Kenneth, H.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

F. Baechle

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338-83-38

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### PATENT COOPERATION TREATY

SEP 1 1 2001

NEEDLE & ROSENBERG P

### **PCT**

# NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

From	the	INTER	रिक्रियो।	DNAL	BURE	ΑU

To:

MILLER, Mary, L. Needle & Rosenberg, P.C. Suite 1200 127 Peachtree Street, N.E. Atlanta, GA 30303-1811 ETATS-UNIS D'AMERIQUE

	, ETAT	rs-unis d'amerio	UE
Date of mailing (day/month/year)			
30 August 2001 (30.08.01)	<u> </u>		
Applicant's or agent's file reference 14114.0353P1		IMPORTANT NO	OTIFICATION
	Internatio	nal filing date (day/mont	th/vear)
International application No.		1arch 2000 (24.03.0	· ·
PCT/US00/07828	24 10		~,
The following indications appeared on record concerning:      The applicant the inventor	the agen	t the cor	nmon representative
Name and Address		State of Nationality	State of Residence
THE GOVERNMENT OF THE UNITED		US	US
STATES OF AMERICA as represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES		Telephone No.	
Centers for Disease Control and		Facsimile No.	
Prevention 255 East Paces Ferry Road - N.E. Room 500			
Atlanta, GA 30333		Teleprinter No.	
United States of America			
The International Bureau hereby notifies the applicant that the X the person X the name X the add		change has been record	ded concerning:
Name and Address		State of Nationality	State of Residence
THE GOVERNMENT OF THE UNITED		US	US
STATES OF AMERICA as represented by THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES	•	Telephone No.	
Centers for Disease Control and Prevention		Facsimile No.	
Technology Transfer Office 1600 Clifton Road, N.E. MS E-67		i acsimile ivo.	
Atlanta CA 20222		mlm/B	4B/TmH
Atlanta, UA 30333		Teleprinter No. DO	4B/TMH DOKETED . 1
Atlanta, GA 30333 United States of America		mlm/BI	4B/TMH DCKETED W Date 9/196/
United States of America  3. Further observations, if necessary:		mlm/BI	
		Teleprinter No. Do	
		Teleprinter No. Do	nH 9 21/01
		Teleprinter No. Do	nH 9 21/01
3. Further observations, if necessary:		Teleprinter No. Do	NH 9 21 101 Name/Date
3. Further observations, if necessary:  4. A copy of this notification has been sent to:		Teleprinter No. Do	NH 9 21 /01 Name/Date

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

Beatriz LARGO

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35

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PATENT COOPERATION TREATY

## **PCT**

RECT 3 0 AUG 2001

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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's	or ager	nt's file reference	COD EUDTHED ACTION	See Notific	ation of Transmittal of International
68018/63	14		FOR FURTHER ACTION	Preliminary	Examination Report (Form PCT/IPEA/416)
Internationa	l applic	ation No.	International filing date (day/monti	h/year)	Priority date (day/month/year)
PCT/US0			24/03/2000		31/03/1999
Internationa C12Q1/70		nt Classification (IPC) or	national classification and IPC		
Applicant					
THE GOV	/ERN	MENT OF THE UN	IITED STATES OF AMet al.		
1. This in and is	nterna trans	tional preliminary exa mitted to the applicar	amination report has been prepare at according to Article 36.	d by this Inte	ernational Preliminary Examining Authority
2. This F	REPO	RT consists of a total	of 5 sheets, including this cover s	sheet.	
b (s	een ai see Ru	mended and are the l	pasis for this report and/or sneets and/or sneets are also as the Administrative Instruct	containing re	on, claims and/or drawings which have ectifications made before this Authority the PCT).
		_			
3. This r	eport	contains indications i	elating to the following items:		
3. This r	_	contains indications r	elating to the following items:		
	<b>⊠</b>	Basis of the report Priority			
ı	<b>⊠</b>	Basis of the report Priority	elating to the following items: of opinion with regard to novelty, in	ventive step	and industrial applicability
1 11	<b>X</b>	Basis of the report Priority Non-establishment of Lack of unity of inve	of opinion with regard to novelty, in		
1 11 111	<b>X</b>	Basis of the report Priority Non-establishment of Lack of unity of inve	of opinion with regard to novelty, in		and industrial applicability entive step or industrial applicability;
         V	<b>X</b>	Basis of the report Priority Non-establishment of Lack of unity of inve Reasoned statement citations and explant Certain documents	of opinion with regard to novelty, in ntion t under Article 35(2) with regard to ations suporting such statement cited		
I II IV V		Basis of the report Priority Non-establishment of Lack of unity of inve Reasoned statemen citations and explan Certain documents Certain defects in the	of opinion with regard to novelty, in ntion t under Article 35(2) with regard to ations suporting such statement cited e international application		
IIIIIV V		Basis of the report Priority Non-establishment of Lack of unity of inve Reasoned statemen citations and explan Certain documents Certain defects in the	of opinion with regard to novelty, in ntion t under Article 35(2) with regard to ations suporting such statement cited		
        V       	8	Basis of the report Priority Non-establishment of Lack of unity of inve Reasoned statemen citations and explan Certain documents Certain defects in the	of opinion with regard to novelty, in ntion t under Article 35(2) with regard to ations suporting such statement cited e international application s on the international application		entive step or industrial applicability;
        V       	M M M M M M M M M M M M M M M M M M M	Basis of the report Priority Non-establishment of Lack of unity of inve Reasoned statement citations and explant Certain documents Certain defects in the Certain observations	of opinion with regard to novelty, in ntion t under Article 35(2) with regard to ations suporting such statement cited e international application s on the international application	novelty, inv	entive step or industrial applicability;
IIIIIV V VI VIII VIIII  Date of sub	omission of the company of the compa	Basis of the report Priority Non-establishment of Lack of unity of inve Reasoned statement citations and explant Certain documents Certain defects in the Certain observations	of opinion with regard to novelty, in ntion t under Article 35(2) with regard to ations suporting such statement cited e international application s on the international application  Date of 27.08. Ional Author	f completion of	entive step or industrial applicability;

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/07828

I.	<b>Basis</b>	of the	report
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1. With regard to the elements of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)): Description, pages: as originally filed 1-47,49-79 Claims, No.: as originally filed 1-46 Drawings, sheets: as originally filed 1/2-2/2 Sequence listing part of the description, pages: 49-79, as originally filed 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language: , which is: the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)). ☐ the language of publication of the international application (under Rule 48.3(b)). ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3). 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing: contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. ☑ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence

Form PCT/IPEA/409 (Boxes I-VIII, Sheet 1) (July 1998)

listing has been furnished.

4. The amendments have resulted in the cancellation of:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/07828

		the description,	pages:		
		the claims,	Nos.:		
		the drawings,	sheets:		
5.		This report has been considered to go bey	establishe ond the dis	d as if (so sclosure a	ome of) the amendments had not been made, since they have been as filed (Rule 70.2(c)):
		(Any replacement shoreport.)	eet contair	ning such	amendments must be referred to under item 1 and annexed to this
6.	Add	litional observations, if	f necessar	y:	
V.	Rea cita	soned statement un tions and explanatio	der Article ons suppo	e 35(2) wi rting suc	ith regard to novelty, inventive step or industrial applicability; h statement
1.	Stat	tement			
	Nov	velty (N)	Yes: No:		6-8,17-19,40-42,45,46 1-5,9-16,20-39,43,44
	Inve	entive step (IS)	Yes: No:	Claims Claims	6-8,17-19,40-42,45,46 1-5,9-16,20-39,43,44
	Ind	ustrial applicability (IA)	Yes: No:	Claims Claims	1-46

- 2. Citations and explanations see separate sheet
- VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

### -AAIIII (AAIII

#### Section V

- D1: WO 98 14611 A (US HEALTH ;KILPATRICK DAVID (US)) 9 April 1998
- D2: OBERSTE ET AL.: 'Molecular evolution of the human enteroviruses: correlation of serotype with VP1 sequence and application to picornavirus classification' JOURNAL OF VIROLOGY, vol. 73, no. 3, 11 February 1999 (electronic publication date as provided by Medline), pages 1941-1948, XP002171810
- Claims 1 -46 refer to methods for detecting and typing an enterovirus in a clinical sample, to oligonucleotide primers for use in said methods and to kits containing said primers.
- D1 and D2, both from the authors of the present application, refer to the same subject-matter. Claims 1-5,9-16,20-39,43 and 44 are anticipated by the disclosure in D1 (see table 1 [primers 1A, 5S, 43A and 61S], figures 1 and 2) and D2 (see table 2 [primers 011,012 and 040], figures 1 and 3).
  - These claims are not novel and do not meet the requirements of Article 33(2) PCT.
- 3. The subject-matter of claims 6-8,17-19,40-42,45 and 46 is distinguished from the closest state of the art by oligonucleotide primers not disclosed in D1 or D2. The problem to be solved by these claims is considered to be the provision of an alternative method to detect and type an enterovirus.
  - Since neither D1 nor D2 contain any information that would allow a skilled person to arrive at the subject-matter of claims 6-8,17-19,40-42,45 and 46 in an obvious way, the claims are considered to be based on an inventive concept and meet the requirements of Article 33(3) PCT).
- 4. The claimed priority date of the present application, 31.03.1999, is valid. Journal of Clinical Microbiology, vol.37, no.5, May 1999, pages 1288-93, does not belong to the state of the art.

# INTERNATIONAL PRELIMINARY

International application No. PCT/US00/07828

### **EXAMINATION REPORT - SEPARATE SHEET**

### **Section VI**

Certain published documents (Rule 70.10)

Application No Patent No

Publication date (day/month/year)

Filing date (day/month/year) Priority date (valid claim) (day/month/year)

WO-A-99/53 097

21.10.1999

06.04.1999

15.04.1998

Should the present application be entered into the regional phase, the above document could be relevant to the question of novelty.

S.1 NTENT COOPERATION TREAT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY MILLER, Mary L. NEEDLE & ROSENBERG P.C. COMMUNICATION IN CASES FOR WHICH 127 Peachtree Street, N.E. NO OTHER FORM IS APPLICABLE Suite 1200 Atlanta, GA 30303-1811 ETATS-UNIS D'AMERIQUE Date of mailing 2 1. 09. 01 (day/month/year) Applicant's or agent's file reference REPLY DUE 14114.0353 See paragraph 1 below 68018/6314 International application No. International filing date (day/month/year) PCT/US 00/07828 24/03/2000 Applicant THE GOVERNMENT OF THE UNITED STATES OF AM...et al. RECEIVED REPLY DUE within \_, months/days from the above date of mailing NO REPLY DUE SEP 2 1 2001 NEEDLE & ROSENBERG COMMUNICATION: Please final herwith enclosed the luternational Prehiminary Examination Report which had been sent emomensly to the slot representative. Please apological for the inconvenience coused.

Name and mailing address of the IPEA/

European Patent Office D-80298 Munich Tcl. (+49-89) 2399-0, Tx; 523656 cpmu d Fax: (+49-89) 2399-4465 Authorized officer

Michela Diglusto



Form PCT/IPEA/424 (January 1994)

(21/09/2001)

ANTO STATE

### PATENT COOPERATION TREATY

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SAMPLES, Kenneth H.
FITCH, EVEN, TABIN & FLANNERY
120 South LaSalle Street
Suite 1600
Chicago, IL 60603
ETATS-UNIS D'AMERIQUE

PCT

NOTIFICATION CONCERNING INFORMAL COMMUNICATIONS WITH THE APPLICANT

(PCT Rule 66.6)

Date of mailing (day/month/year)

27.08.2001

Applicant's or agent's file reference

68018/6314

International application no.

PCT/US00/07828

TRANSMITTAL FOR INFORMATION

International filing date (day/month/year)

24/03/2000

Applicant

THE GOVERNMENT OF THE UNITED STATES OF AM...et al.

An informal communication took place on 23/08/2001, between the International Preliminary Examining Authority and the applicant / the agent.

A copy of the note on that communication (Form PCT/IPEA/428) is herewith transmitted for your information.

Name and mailing address of the international preliminary examining authority

European Patent Office D-80298 Munich

Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Fax: +49 89 2399 - 4465

Authorized officer

Digiusto, M





Vertrag über di Internationale Zusammenarbeit auf des Gebiet des Patentwesens
Patent Cooperation Trea

Traîté de coopération en matière de brevets

### PCT

Application No.:

PCT/US00/07828

Note on an informal communication by telephone with the Applicant

A copy of this note is being sent to the Applicant for information

### **Participants**

Agent:

B. Becker

Examiner(s):

M. Wieser

Summary of the communication

The Applicant was contacted to apologize that the authority in charge of the International preliminary examination was not able to produce the IPER within 28 months from the claimed priority date. The Applicant preferred to receive the IPER immediately, without a first written opinion.

23/08/2001

Date (day / month / year)

THE PROPERTY OF THE PARTY OF TH

M. Wieser

Authorized officer of IPEA

From the

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SAMPLES, Kenneth H.
FITCH, EVEN, TABIN & PLANNERY
120 South LaSalle Street
Suite 1600
Chicago, IL 66603

ETATS-UMS D'AMERIQUE

INNERY ELECA
NEEDLE DE LECA
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EN COOLENIATIVES
EN COOLENIATIVES

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing (day/month/year)

27.08.2001

Applicant's or agent's file reference

68018/6314

IMPORTANT NOTIFICATION

International application No. PCT/US00/07828

International filing date (day/month/year) 24/03/2000 Priority date (day/month/year)

31/03/1999

Applicant

THE GOVERNMENT OF THE UNITED STATES OF AM., et al.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the International preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

Authorized officer

Digiusto, M



European Patent Office
D-80298 Munich
Tol. (49.89.9399.0. TV: 523656.enm) d



Fax: +49 89 2399 - 4465

Tel.+49 89 2399-8162



·Form PCT/IPEA/416 (July 1992)



# **PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's	or ag	ent's file reference		See N	otification of Transmittal of Internat	tional
68018/6	314		FOR FURTHER A		linary Examination Report (Form P	
Internation	al app	ication No.	International filing date (	day/month/year)	Priority date (day/month/yea	ar)
PCT/US	00/07	7828	24/03/2000		31/03/1999	
		ent Classification (IPC) or na	tional classification and IP	C		
C12Q1/	/ U					
Applicant			ED OTATES OF AM	املما		
THE GC	VER	NMENT OF THE UNIT	ED STATES OF AM.	et al.		
				prepared by this	International Preliminary Exam	mining Authority
and	s tran	smitted to the applicant a	according to Article 36,			
a Thia	DEDA	PRT consists of a total of	5 cheets including this	cover sheet		
2. This	NEFC	THE CONSISTS OF A COLAF CE	a etteetet tilemettiä rus	a cover eneer		
	This re	port is also accompanie	d by ANNEXES, i.e. sho	eets of the descri	iption, claims and/or drawlings	which have
	seen a see R	imenced and are the bas ule 70.16 and Section 6	of the Administrative	instructions und	g rectifications made before the rectifications of the rectifications.	is Authority
Thos	·	exes consist of a total of	cheets			
1 168	e ann	exes colleist of a total of	2116-9121	•		
		t 1				•
3. This	report	contains indications rela	iting to the following iter	ns:	•	
	×	Basis of the report				
11						i
111			•	velty, inventive s	step and industrial applicability	
IV		Lack of unity of invention				allaa hilib z
۷	M	citations and explanation			inventive step or industrial app	oncability;
V١	X	Certain documents cité	ad			
VII		Certain defects in the in	• •			
VIII		Certain observations or	n the international applic	eation		
Date of su	omissio	on of the demand		Dat of completion	on of this report	
17/10/20	00			27,08.2001		
		g address of the internations ining authority:	ll .	Authorized office	ſ	STORE MICHOLINA
	Euro	opean Patent Office 0298 Munich		Mionou M		
<i><u>)</u></i>		1298 munica +49 89 2399 • D. Tx: 523656	sepmu d	Wieser, M		

Fax: +49 89 2399 - 4465

Telephone No. +49 89 2399 8434

Form PCT/IPEA/409 (cover sheet) (January 1994)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/07828

ı.	Ва	sis of the report	
1.	the and	receiving Office in	ments of the international application (Replacement sheets which have been furnished to response to an invitation under Article 14 are referred to in this report as "originally filed" o this report since they do not contain amendments (Rules 70.16 and 70.17)):
	1-4	17,49-79	as originally filed
	Cla	aims, <b>No.</b> :	
	1-4	<b>.</b> 6	as originally filed
	Dra	awings, sheets:	
	1/2	-2/2	as originally filed
	Sec	quence listing par	of the description, pages:
	49-	79, as originally file	d
2.			guage, all the elements marked above were available or furnished to this Authority in the international application was filed, unless otherwise indicated under this item.
	The	ese elements were a	available or furnished to this Authority in the following language: , which is:
		• -	translation furnished for the purposes of the international search (under Rule 23.1(b)).
		,	iblication of the international application (under Rule 48.3(b)).
		the language of a 55.2 and/or 55.3).	translation furnished for the purposes of international preliminary examination (under Rule
3.			leotide and/or amino acid sequence disclosed in the international application, the y examination was carried out on the basis of the sequence listing:
	×	contained in the in	ternational application in written form.
		filed together with	the international application in computer readable form.
		_	ently to this Authority in written form.
	×	•	ently to this Authority in computer readable form.
	×	The statement that	t the subsequently furnished written sequence listing does not go beyond the disclosure in oplication as filed has been furnished.

The statement that the Information recorded in computer readable form is identical to the written sequence

4. The amendments have resulted in the cancellation of:

listing has been furnished.

### INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/US00/07828

	the description,	pages:
	the claims,	Nos.:
	the drawings,	sheets:
5. 🗆	This report has be considered to go b	en established as if (some of) the amendments had not been made, since they have been beyond the disclosure as flied (Rule 70.2(c)):
	(Any replacement report.)	sheet containing such amendments must be referred to under item 1 and annexed to this
	• •	

- 6. Additional observations, if necessary:
- V. Reasoned statement under Article 35(2) with regard to novelty, Inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes:

Claims 6-8,17-19,40-42,45,46

No:

Claims 1-5,9-16,20-39,43,44

Inventive step (IS)

Yes:

Claims 6-8,17-19,40-42,45,46

No:

Claims 1-5,9-16,20-39,43,44

Industrial applicability (IA)

Yes:

Claims 1-46

No:

Claims

2. Citations and explanations see separate sheet

#### VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

# INTERNATIONAL PRELIMINARY International application No. PCT/US00/07828 EXAMINATION REPORT - SEPARATE SHEET

### Section V

D1: WO 98 14611 A (US HEALTH ;KILPATRICK DAVID (US)) 9 April 1998

D2: OBERSTE ET AL.: 'Molecular evolution of the human enteroviruses: correlation of serotype with VP1 sequence and application to picornavirus classification' JOURNAL OF VIROLOGY, vol. 73, no. 3, 11 February 1999 (electronic publication date as provided by Medline), pages 1941-1948, XP002171810

- 1. Claims 1 -46 refer to methods for detecting and typing an enterovirus in a clinical sample, to oligonucleotide primers for use in said methods and to kits containing said primers.
- 2. D1 and D2, both from the authors of the present application, refer to the same subject-matter. Claims 1-5,9-16,20-39,43 and 44 are anticipated by the disclosure in D1 (see table 1 [primers 1A, 5S, 43A and 61S], figures 1 and 2) and D2 (see table 2 [primers 011,012 and 040], figures 1 and 3).

These claims are not novel and do not meet the requirements of Article 33(2) PCT.

- 3. The subject-matter of claims 6-8,17-19,40-42,45 and 46 is distinguished from the closest state of the art by oligonucleotide primers not disclosed in D1 or D2. The problem to be solved by these claims is considered to be the provision of an alternative method to detect and type an enterovirus.
  - Since neither D1 nor D2 contain any information that would allow a skilled person to arrive at the subject-matter of claims 6-8,17-19,40-42,45 and 46 in an obvious way, the claims are considered to be based on an inventive concept and meet the requirements of Article 33(3) PCT).
- 4. The claimed priority date of the present application, 31.03.1999, is valid. Journal of Clinical Microbiology, vol.37, no.5, May 1999, pages 1288-93, does not belong to the state of the art.

## INTERNATIONAL PRELIMINARY

International application No. PCT/US00/07828

### **EXAMINATION REPORT - SEPARATE SHEET**

### Section VI

Certain published documents (Rule 70.10)

Application No Patent No.

Publication date (day/month/year)

Filing date (day/month/year) Priority date (valid claim) (day/month/year)

WO-A-99/53 097

21.10.1999

06.04.1999

15.04.1998

Should the present application be entered into the regional phase, the above document could be relevant to the question of novelty.





From the INTERNATIONAL SEARCHING AUTHORITY

NEEDLE & ROSENBERG, P.C.

NOTIFICATION OF TRANSPITTED OF THE INTERNATIONAL SEARCH REPORATIONAL

Suite 1200	OR THE DECLARATION
Attn. SPRATT, Gwendolyn D. The Candler Building	
127 Peachtree Street, N.E.	(PCT Rule 44.1)
Atlanta, GA 30303-1811	
UNITED STATES OF AMERICA	
·	Du et e
	Date of mailing (day/month/year) 24/07/2001
Applicant's or agent's file reference	
68018 14/14.0353Pl	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No.	International filing date
PCT/US 00/07828	(day/month/year) 24/03/2000
Applicant	
THE GOVERNMENT OF THE UNITED STATES OF A	MERICA as
1. X The applicant is hereby notified that the International Search	h Report has been established and is transmitted herewith.
Filing of amendments and statement under Article 19:	and the leterantianal Application (see Bule 46):
The applicant is entitled, if he so wishes, to amend the clair	ns of the International Application (see Aule 40).
When? The time limit for filing such amendments is normal	ally 2 months from the date of transmittal of the
International Search Report; however, for more de	MLM/BAB/TMH
Where? Directly to the International Bureau of WIPO	DOCKETED ,
34, chemin des Colombettes 1211 Geneva 20, Switzerland	5/0 Dots 7/2 5/0
Fascimile No.: (41–22) 740.14.35	
For more detailed instructions, see the notes on the acco	
2. The applicant is hereby notified that no International Search	Name/Date  Name/Date
Article 17(2)(a) to that effect is transmitted herewith.	Trioport will be combined and that the designation area.
3. With regard to the protest against payment of (an) addition	onal fee(s) under Rule 40.2, the applicant is notified that:
	n transmitted to the International Bureau together with the
applicant's request to forward the texts of both the pro	test and the decision thereon to the designated Offices.
	·
no decision has been made yet on the protest; the app	olicant will be notified as soon as a decision is made.
4. Further action(s): The applicant is reminded of the following:	·
Shortly after 18 months from the priority date, the international a	onlication will be published by the International Bureau.
If the applicant wishes to avoid or postpone publication, a notice priority claim, must reach the International Bureau as provided completion of the technical preparations for international publications.	e of withdrawal of the international application, or of the in Rules 90 <i>bis</i> .1 and 90 <i>bis</i> .3, respectively, before the
Within 19 months from the priority date, a demand for internation wishes to postpone the entry into the national phase until 30 mg	al preliminary examination must be filed if the applicant on the priority date (in some Offices even later).
Within 20 months from the priority date, the applicant must perfo before all designated Offices which have not been elected in the priority date or could not be elected because they are not bound.	ie demand or in a later election within 19 months from the

Name and r	nailing address of	the Internation	nal Searching	Authority
	European Patent	Office P.B. 5	818 Patentiaa	n 2

Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016

Authorized officer

Catherine Humbert

#### NOTES 7 RM PCT/ISA/220



These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

#### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

ولي المالية

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new:
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

### The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
   "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]:

   "Claims 1 to 15 replaced by amended claims 1 to 11."
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
   "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
   "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

#### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

#### It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.



(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	(Form PCT/ISA/2	of Transmittal of International Search Report 20) as well as, where applicable, item 5 below.
68018	ACTION	
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/US 00/07828	CT/US 00/ 07828 24/03/2000	
Applicant		
THE GOVERNMENT OF THE UNI	TED STATES OF AMERICA as	
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searching Auth nsmitted to the International Bureau.	nority and is transmitted to the applicant
This International Search Report consists  It is also accompanied by	of a total of3 sheets. a copy of each prior art document cited in this	report.
1. Basis of the report		the state of the s
	international search was carried out on the bas ess otherwise indicated under this item.	sis of the international application in the
the international search w Authority (Rule 23.1(b)).	as carried out on the basis of a translation of the	ne international application furnished to this
b. With regard to any <b>nucleotide an</b> was carried out on the basis of the		ternational application, the international search
1 =	rnational application in computer readable form	1.
furnished subsequently to	this Authority in written form.	
T furnished subsequently to	this Authority in computer readble form.	
the statement that the sub international application a	sequently furnished written sequence listing do s filed has been furnished.	pes not go beyond the disclosure in the
		identical to the written sequence listing has been
2. Certain claims were fou	nd unsearchable (See Box I).	
3. Unity of invention is lack	king (see Box II).	
4. With regard to the <b>title</b> ,		
the text is approved as su	bmitted by the applicant.	
the text has been establish	ned by this Authority to read as follows:	
5. With regard to the abstract,		
the text is approved as su	• • • •	The applicant area
	ned, according to Rule 38.2(b), by this Authority date of mailing of this international search rep	
6. The figure of the <b>drawings</b> to be publi	shed with the abstract is Figure No.	
as suggested by the applic		X None of the figures.
because the applicant faile		
because this figure better	characterizes the invention.	

# A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C12Q1/70

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

K. P. P. P. C.

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, MEDLINE

	IENTS CONSIDERED TO BE RELEVANT		<del></del>
Category °	Citation of document, with indication, where appropriate, of	Relevant to claim No.	
X	WO 98 14611 A (US HEALTH ;KIL (US)) 9 April 1998 (1998-04-0	1-6, 9-17, 20-39, 43,44	
A	figures 1,2		7,8,18, 19, 40-42, 45,46
		-/	
X Furt	her documents are listed in the continuation of box C. ,	X Patent family members are liste	d in annex.
Consider	ategories of cited documents :	*T* later document published after the in	ternational filing date
Special ca		or priority date and not in conflict with	th the application but
'A* docume	ent defining the general state of the art which is not dered to be of particular relevance	cited to understand the principle or t	heory underlying the
'A* docume consid	dered to be of particular relevance document but published on or after the international	cited to understand the principle or to invention  "X" document of particular relevance; the considered poyel or cannot be considered to the considered poyel or cannot be considered by the con	claimed invention
'A" docume consid 'E" earlier of filing of 'L" docume which	dered to be of particular relevance document but published on or after the international date ent which may throw doubts on priority claim(s) or is cited to establish the publication date of another	cited to understand the principle or to invention  "X" document of particular relevance; the cannot be considered novel or cannot involve an inventive step when the Canton invention in particular relevance; the	ctaimed invention of be considered to focument is taken alone ctaimed invention
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(Continua ategory °	cition) DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
acegury	Onation of Goodinesis, with introducion, where appropriate, of the relevant passages	neevan to Gain No.
(	OBERSTE ET AL.: "Molecular evolution of the human enteroviruses: correlation of serotype with VP1 sequence and application to picornavirus classification" JOURNAL OF VIROLOGY, vol. 73, no. 3,	1-6, 9-17, 20-39, 43,44
4	11 February 1999 (1999-02-11), pages 1941-1948, XP002171810 figures 1,3; table 2	7,8,18,
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P,X	OBERSTE ET AL.: "Typing of human enteroviruses by partial sequencing of VP1"  JOURNAL OF CLINICAL MICROBIOLOGY, vol. 37, no. 5, May 1999 (1999-05), pages 1288-1293, XP002171811 abstract; figures 1,2; table 1	1-5, 9-16, 20-39, 43,44
, X	WO 99 53097 A (US HEALTH ;KILPATRICK DAVID R (US)) 21 October 1999 (1999-10-21)	1-5, 9-16, 20-39, 43,44
	claims 1-6; examples 1-3; tables 1-5	10,11
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